



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/701,887	11/04/2003	Steffen Nock	020144-002110US	6724
20350 7590 12/19/2006 TOWNSEND AND TOWNSEND AND CREW, LLP TWO EMBARCADERO CENTER EIGHTH FLOOR SAN FRANCISCO, CA 94111-3834			EXAMINER KIM, YUNSOO	
			ART UNIT	PAPER NUMBER
			1644	
SHORTENED STATUTORY PERIOD OF RESPONSE		MAIL DATE	DELIVERY MODE	
3 MONTHS		12/19/2006	PAPER	

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

**Office Action Summary**

Application No.

10/701,887

Applicant(s)

NOCK ET AL.

Examiner

Yunsoo Kim

Art Unit

1644

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 19 September 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 25-27 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 25-27 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### DETAILED ACTION

1. Claims 25-27 are pending.
2. In view of Applicants' amendment to the specification, the objection set forth in the office action mailed 6/23/06 has been withdrawn.
3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

4. Claims 25-27 stand rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Pat. No. 5,099,005 (of record) in view of Kim et al. (Journal of Biol. Chem. 1994, vol. 269, pp. 12345-12350, of record), U.S. Pat. No. 6,358,710 (of record) and Pierce Product Information for ImmunoPure® IgG1 Fab and F(ab')<sub>2</sub> preparation kit (of record) and U.S. Pat. No. 4,281,061 (of record) for the reasons set forth in the office action mailed 6/23/06.

Applicants' arguments filed 9/19/06 have been fully considered but they were not persuasive.

Applicants' traversed the rejection based on that the cited references failed to teach all limitations of the pending claims and it's not obvious to combine reference teachings.

Art Unit: 1644

Applicants argue that the '005 patent only teaches that the antibodies should be treated with a sialidase only and the glycosylated antibody contains one or more non-hinge regions that are adjacent to the hinge region and have one or more attached oligosaccharide groups have not taught. Applicants further argue that the teachings of the '710 patent is merely a generic description of what types of glycosylation may exist in an immunoglobulin and how the glycoylation can be modified and does not reflect general knowledge in the field of antibody molecules.

Contrary to applicants' argument, the '005 patent teaches use of pepsin or papain treatment for production of F(ab)'<sub>2</sub> fragments (col. 6, lines 34-40, in particular). In addition, the structural limitation of antibody having glycosylated antibody contains one or more non-hinge regions that are adjacent to the hinge region and have one or more attached oligosaccharide groups was taught by the Kim et al. reference (p. 12345, in particular). The hinge region of an antibody is located where the globular portions of the antibody joined by a flexible stretch of a polypeptide chain. As taught by Kim et al., the IgG molecules possess conserved glycosylation site at Asn-297 in the CH-2 (e.g. adjacent to hinge region) domain of heavy chains (see introduction, p. 12345, col. 1, in particular). Thus, the structural limitation of antibody having glycosylated antibody contains one or more non-hinge regions that are adjacent to the hinge region and have one or more attached oligosaccharide groups is an inherent property of the antibody.

In addition, the '710 patent is drawn to a humanized antibody and the teachings in col. 19-21 are specific for IgG antibody (col. 19, lines 55-65, in particular). Even if the '710 patent only provides a general knowledge in the field of protein glycosylation, the ordinary skill in the art would have been motivated to extrapolate the deglycosylation method in the protein field to deglycosylation of antibody using glycosydases.

Therefore, it would have been obvious to one of the ordinary skill in the art at the time the invention was made to substitute the sialidase treatment prior to a protease treatment in a method of making F(ab)'<sub>2</sub> fragment as taught by the '005 patent with a N-or O-glycosidases as taught by the Kim et al. and the '710 patent and package the glycosidase, proteases, purification medium and instruction into a kit format as taught by the Pierce Kit and the '061 patent.

Art Unit: 1644

One of ordinary skill in the art at the time the invention was made would have been motivated to do so because Kim et al. teach the glycosylation renders the hinge region resistant against the proteolyses of the heavy chains and the '710 patent teaches that the N-linked or O-linked carbohydrates can be removed from the protein molecules by N-glycosidase or O-glycosidase, respectively to make more susceptible to protease treatment to enhance F(ab)'2 fragment production. It is well known in the art to assemble the active ingredients in a kit format as taught by the Pierce product information for convenience, optimization and economy of the users as taught by the '061 patent.

From the teachings of the references, one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was prima facie obvious to one of the ordinary in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Thus, it is the examiner's position that the cited references teach all the limitations of the claimed invention and the combination of teachings remain obvious.

5. No claims are allowable.

6. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yunsoo Kim whose telephone number is 571-272-3176. The examiner can normally be reached on Monday thru Friday 8:30 - 5:00PM.

Art Unit: 1644

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 571-272-0841. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.


Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Yunsoo Kim

Patent Examiner

Technology Center 1600

November 28, 2006

  
CHRISTINA CHAN  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600